REMARKS/ARGUMENTS

Claims 1, 6, 8-21, 25-43 and 45-61 are under examination in the application. Claims 4, 5, 7, 22-24, 44 and 62-80 have been cancelled. The Final Office Action mailed on July 2, 2007 includes the following rejections:

1. Claims 1, 5-22, 24-43 and 45-61 are rejected under 35 U.S.C. § 103(a).

Claim Rejections – Claims 1, 5-22, 24-43 and 45-61are rejected under 35 U.S.C. § 103(a)

The Action rejects claims 1, 5-22, 24-43 and 45-61under 35 U.S.C. § 103(a) as being unpatentable over Devane, et al., U.S. Patent No. 6,228,398 (Devane), in view of Dang, et al., U.S. Patent No. 6,462,094 (Dang) and U.S. Patent Application No. 2003/0049318 (Davis).

The Action combines Devane, Dang and Davis to establish a *prima facie* case of obviousness. However, there is neither a reasonable expectation of success to achieve the present invention, nor do the combined references teach or suggest all the claim limitations. MPEP § 2143; *In re Vacek*, 947 F.2d 488 (Fed. Cir. 1991).

First, Applicants traverse the argument made in the Action at page 3 that "once a pharmaceutical composition is disclosed in the prior art it is well within the purview of the skilled artisan to substitute one drug for another in a single composition." In fact, the skilled artisan knows that it is not a trivial matter to combine and prepare stable pharmaceutical compositions. If the matter were as trivial as the Action argues, then textbooks such as REMINGTON: THE SCIENCE AND PRACTICE OF PHARMACY, 20th Edition. Baltimore, MD: Lippincott Williams & Wilkins, 2000, would not need to be 2077 pages, have 620 figures and 352 tables.

Second, Applicants further traverse the statement made in the Action at page 3 that "[u]sing traditional spray-coating, there is not was to apply exactly "three or more layers"." The skilled artisan knows that each time that a spray-coating event is conducted on a pharmaceutical product that a single layer is being added to the target pharmaceutical. In fact, the skilled artisan knows not only the number of layers added to the target pharmaceutical but the exact thickness of each, within well-known parameters. Furthermore, the regulatory requirements of agencies like the USDA and the FDA have stringent controls over the thickness, stability and release profiles that are achieved during the manufacturing process.

Looking closely at the release profile in Devane the product taught therein for immediate release

only provides 50% of its' first active in about 2 hours. Second, Devane's extended, pulsatile release only achieves 50% release by about 6 hours. Therefore, the skilled artisan using Devane could not achieve the present invention as the release profiles taught by Devane fail to achieve the claimed release profiles. Devane is not enabling as to any other modification of the release profile or how to modify those release profiles and in fact claims (e.g., claim 19) release profiles of 50 to 100% within four hours (as shown in Devane Figure 1) and 25 to 55% between four to eight hours. Looking at Devane Table 4, the skilled artisan learns that between 76 and 87% release is only obtained at 10 hours. Also looking at Tables 3 and 4, the skilled artisan learns that a maximum of 50.5% release was obtained after one hour.

Dang teaches a conventional tablet prepared by well-known conventional tabletting techniques that includes phenylephrine tannate and guaifenesin. Dang does not teach a first active available for immediate release and a second active for extended release that are released during the required timeframes or the manner to achieve the claim release. Even if the skilled artisan would have been motivated to combine Dang and Devane, as argued hereinabove, Devane fails to add the missing preparation of the release profiles as claimed.

Davis teaches a drug product having two portions both of which contain guaifenesin. Davis teaches a compressed bi-layer tablet with an immediate release formulation of guaifenesin and a delayed release matrix formulation of guaifenesin, Davis does not teach an enveloped formulation that combines a first active on a carrier and a second active on a carrier. The delayed release matrix formulation of Davis is simply a media that when exposed to low pH forms a gel from which the guaifenesin diffuses. Using the teachings in Davis the skilled artisan would not be able to achieve the present invention, no matter how much motivation to combine may exist. Again, even if the skilled artisan would have been motivated to combine Devane, Dang and Davis, as argued hereinabove, Devane fails to add the missing preparation of the release profiles as claimed.

Accordingly, Applicants respectfully submit that claims 1, 6, 8-21, 25-43 and 45-61 are not obvious over Devane, Dang and Davis, therefore, allowable under 35 U.S.C. § 103(a). For the reasons mentioned above, the Applicants respectfully request the withdrawal of the rejection under 35 U.S.C. § 103.

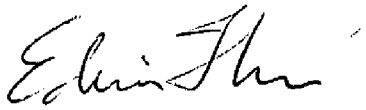
Conclusion

Accordingly, after entry of this Amendment, the claims numbering has been corrected, original Claims 1, 6, 8-21, 25-43 and 45-61 are pending in the above-identified Application. Withdrawal of the objections and rejections and an early Notice of Allowance are earnestly requested.

The Examiner is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the present application.

Dated: September 4, 2007.

Respectfully submitted,



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